

ABRYSVO- respiratory syncytial virus vaccine

Pfizer Laboratories Div Pfizer Inc

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ABRYSVO safely and effectively. See full prescribing information for ABRYSVO.

ABRYSVO™ (Respiratory Syncytial Virus Vaccine) solution for intramuscular injection
Initial U.S. Approval: 2023

INDICATIONS AND USAGE

ABRYSVO is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older. (1)

DOSAGE AND ADMINISTRATION

- **For intramuscular use only.** (2)
- Administer ABRYSVO as a single approximately 0.5 mL dose. (2.3)

DOSAGE FORMS AND STRENGTHS

Solution for injection. A single dose after reconstitution is approximately 0.5 mL. (3)

CONTRAINDICATIONS

History of severe allergic reaction (e.g., anaphylaxis) to any component of ABRYSVO. (4)

ADVERSE REACTIONS

The most commonly reported solicited local and systemic adverse reactions ($\geq 10\%$) were fatigue (15.5%), headache (12.8%), pain at the injection site (10.5%), and muscle pain (10.1%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer Inc. at 1-800-438-1985 or VAERS at 1-800-822-7967 or <http://vaers.hhs.gov>.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 5/2023

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ABRYSVO is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.

2 DOSAGE AND ADMINISTRATION

2.1 Dose and Schedule

Administer a single dose (approximately 0.5 mL) of ABRYSVO intramuscularly.

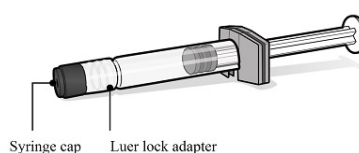
2.2 Preparation for Administration

ABRYSVO is supplied in a kit that includes a vial of Lyophilized Antigen Component (a sterile white powder), a prefilled syringe containing Sterile Water Diluent Component and a vial adapter.

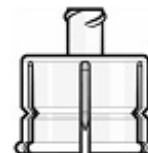
Vial of Lyophilized Antigen Component



Syringe of Sterile Water Diluent Component



Vial Adapter



To form ABRYSV0, reconstitute the Lyophilized Antigen Component with the accompanying Sterile Water Diluent Component as described in the panels below.



Step 1. Preparation of vial and vial adapter

- Remove plastic flip off cap from vial and cleanse the rubber stopper.
- Without removing the vial adapter from its packaging, peel off the top cover.



Step 2. Attachment of vial adapter

- Hold the base of the vial on a flat surface.
- Keep the vial adapter in the packaging and orient it vertically over the center of the vial so that the adapter spike aligns with the center of the vial's rubber stopper.
- Connect the vial adapter to the vial with a straight downward push. The vial adapter will lock into place.
- Do not push vial adapter in at an angle as this may result in leaking during use.
- Remove the vial adapter packaging.



Step 3. Removal of syringe cap

- For all syringe assembly steps, hold the syringe only by the Luer lock adapter located at the tip of the syringe. This will prevent the Luer lock adapter from detaching during use.
- Remove the syringe cap by slowly turning the cap counter-clockwise while holding the Luer lock adapter.



Step 4. Connection of syringe to vial adapter

- Hold the syringe's Luer lock adapter and connect it to the vial adapter by turning clockwise.
- Stop turning when you feel resistance, overtightening the syringe may result in leaking during use.
- Once the syringe is securely attached to the vial adapter, there will be a small space between the top of the vial adapter and the Luer lock adapter of the syringe.



Step 5. Reconstitution of Lyophilized Antigen Component to form ABRYSV0

- Inject the entire contents of the syringe containing the Sterile Water Diluent Component into the vial.
- Do not remove the empty syringe.
- While holding the plunger rod down, gently swirl the vial in a circular motion until the powder is completely dissolved (less than 1 minute).
- Do not shake.



Step 6. Withdrawal of reconstituted vaccine

- Invert the vial completely with the vial adapter and syringe still attached.
- Slowly withdraw the entire contents into the syringe to ensure an approximately 0.5 mL dose of ABRYSV0 for administration.
- Do not pull the plunger rod out.



Step 7. Disconnection of syringe

- Hold the Luer lock adapter of the syringe and disconnect the syringe from the vial adapter by turning counter-clockwise.



Step 8. Attachment of needle

- Attach a sterile needle suitable for intramuscular injection to the syringe containing ABRYSV0.



Step 9. Visual inspection

- ABRYSV0 is a clear and colorless solution.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Discard if either condition is present.

2.3 Administration

For intramuscular injection only

After reconstitution, administer ABRYSV0 immediately or store at room temperature [15°C to 30°C (59°F to 86°F)] and use within 4 hours. Discard reconstituted vaccine if not used within 4 hours.

3 DOSAGE FORMS AND STRENGTHS

ABRYSV0 is a solution for injection. A single dose after reconstitution is approximately 0.5 mL.

4 CONTRAINDICATIONS

Do not administer ABRYSV0 to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of ABRYSV0 [see Description (11)].

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an anaphylactic reaction occurs following administration of ABRYSV0.

5.2 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, including ABRYSV0. Procedures should be in place to avoid injury from fainting.

5.3 Altered Immunocompetence

Immunocompromised individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to ABRYSV0.

5.4 Limitations of Vaccine Effectiveness

Vaccination with ABRYSV0 may not protect all vaccine recipients.

6 ADVERSE REACTIONS

In clinical trials, the most commonly reported ($\geq 10\%$) adverse reactions were fatigue (15.5%), headache (12.8%), pain at the injection site (10.5%), and muscle pain (10.1%).

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

The safety of ABRYSV0 was evaluated in Study 1 (NCT05035212) in which 17,215 participants received ABRYSV0 and 17,069 received placebo (0.5 mL dose, containing the same buffer ingredients in the same quantities as in a single dose of ABRYSV0 [see *Description (11)*]). Study 1 is an ongoing Phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of ABRYSV0 in individuals 60 years of age and older. This study is being conducted in the USA, South Africa, Japan, Canada, Finland, the Netherlands, and Argentina. Demographic characteristics among participants who received ABRYSV0 and those who received placebo were generally similar with regard to age, sex, race, and ethnicity. Of the participants in the study, 51% were male and 78% were White, 13% were Black or African American, and 37% were Hispanic/Latino. The median age of participants was 67 years (range 59-97 years).

Solicited local and systemic reactions were collected using electronic diaries for 7 days after study vaccination in 7,169 participants (3,630 ABRYSV0 participants and 3,539 placebo recipients) from a subset of sites. For all participants, unsolicited adverse events were collected for one month after study vaccination; serious adverse events (SAEs) are collected throughout study participation.

Solicited Local and Systemic Reactions in Study 1

Solicited local and systemic reactions reported within 7 days after vaccination in Study 1 are presented in Tables 1 and 2.

Table 1 Percentage of Participants with Local Reactions Reported, by Maximum Severity, within 7 Days after Vaccination - Study 1*

Local Reactions	ABRYSV0	PLACEBO
-----------------	---------	---------

	N=3,619-3,621[†] %	N=3,532-3,539[†] %
Injection site pain[‡]		
Any [§]	10.5	6.0
Mild	9.4	5.3
Moderate	1.1	0.7
Severe	<0.1	0
Redness^{§¶}		
Any [§]	2.7	0.7
Mild	1.5	0.5
Moderate	1.1	0.2
Severe	0.1	0
Swelling^{§¶}		
Any [§]	2.4	0.5
Mild	1.5	0.2
Moderate	0.9	0.2
Severe	0.1	<0.1

* NCT05035212

† N = number of participants who provided e-diary data for a specific reaction after vaccination.

‡ Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity.

§ Any includes all participants who reported a reaction as mild, moderate, or severe during Day 1 to Day 7 after vaccination.

¶ Mild: 2.5 cm to 5 cm; moderate: >5 cm to 10 cm; severe: >10 cm (for data reported from e-diaries).

Table 2 Percentage of Participants with Systemic Reactions Reported, by Maximum Severity, within 7 Days after Vaccination - Study 1*

Systemic Reactions	ABRYSVO N=3,619-3,621[†] %	PLACEBO N=3,532-3,539[†] %
Fever ($\geq 38.0^{\circ}\text{C}$)		
$\geq 38.0^{\circ}\text{C}$	1.4	1.4
38.0°C to 38.4°C	0.6	0.8
$>38.4^{\circ}\text{C}$ to 38.9°C	0.8	0.6
$>38.9^{\circ}\text{C}$ to 40.0°C	<0.1	<0.1
$>40.0^{\circ}\text{C}$	0	<0.1
Fatigue[‡]		
Any [§]	15.5	14.4
Mild	9.3	8.4
Moderate	5.9	5.8
Severe	0.3	0.1

Headache [†]		
Any [§]	12.8	11.7
Mild	9.0	8.4
Moderate	3.7	3.2
Severe	0.1	<0.1
Muscle pain [‡]		
Any [§]	10.1	8.4
Mild	6.5	5.5
Moderate	3.5	2.8
Severe	0.2	<0.1
Joint pain [‡]		
Any [§]	7.5	6.9
Mild	4.5	3.9
Moderate	2.9	2.9
Severe	<0.1	<0.1
Nausea [‡]		
Any [§]	3.4	3.7
Mild	2.5	3.1
Moderate	0.9	0.6
Severe	0	<0.1
Vomiting [¶]		
Any [§]	0.9	0.8
Mild	0.7	0.7
Moderate	0.2	0.1
Severe	0	<0.1
Diarrhea [#]		
Any [§]	5.9	5.2
Mild	4.4	4.2
Moderate	1.3	0.9
Severe	0.1	0.1

* NCT05035212

† N = number of participants who provided e-diary data for a specific reaction after vaccination.

‡ Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily routine activity.

§ Any includes all participants who reported a reaction as mild, moderate, or severe during Day 1 to Day 7 after vaccination.

¶ Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration.

Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours.

Solicited local and systemic reactions had a median duration of 1-2 days.

Unsolicited Adverse Events in Study 1

Unsolicited adverse events occurring within 1 month after vaccination were similar between groups, reported in 8.9% and 8.5% of participants who received ABRYVO and placebo, respectively.

Within 30 days after vaccination, atrial fibrillation was reported in 10 vaccine recipients and 4 placebo recipients (of which 4 in the ABRYSV0 group and 3 in the placebo group were serious adverse events); the onset of symptoms was 18 to 30 days post vaccination. The currently available information on atrial fibrillation is insufficient to determine a causal relationship to the vaccine. There were no other notable patterns or numerical imbalances between groups for specific categories of unsolicited adverse events.

Serious Adverse Events in Study 1

In Study 1, SAEs were reported by 2.3% of participants in both the ABRYSV0 and placebo groups. Three participants in the ABRYSV0 group had SAEs which were assessed as possibly related to study vaccination: Guillain-Barre Syndrome reported 7 days after vaccination, Miller Fisher Syndrome reported 8 days after vaccination, and hypersensitivity reported 8 hours after vaccination.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriages in clinically recognized pregnancies is 2% to 4%, and 15% to 20%, respectively, and the estimated background risk of fetal deaths after 20 weeks is 0.6%. ABRYSV0 is not approved for use in individuals younger than 60 years of age.

Data from a clinical trial (NCT04424316) that enrolled pregnant individuals who were randomly assigned 1:1 to receive ABRYSV0 or placebo (0.5 mL dose, containing the same buffer ingredients in the same quantities as in a single dose of ABRYSV0 [see *Description (11)*]) at 24 through 36 weeks' gestation revealed no evidence for vaccine-associated increase in the risk of congenital anomalies or fetal deaths. In this study, there was a numerical imbalance in preterm births, with more preterm infants born to individuals in the ABRYSV0 group compared to individuals in the placebo group (see *Human Data*).

A developmental and reproductive toxicity study was performed in female rabbits administered a vaccine formulation containing two times the antigen content of a single human dose of ABRYSV0 prior to and during gestation. The study showed no evidence of harm to the fetus or to postnatal survival, growth, or development (see *Animal Data*).

Data

Human Data

In a randomized controlled clinical trial (NCT04424316), 3,682 pregnant individuals received ABRYSV0 and 3,676 received placebo (0.5 mL dose, containing the same buffer ingredients in the same quantities as in a single dose of ABRYSV0 [see *Description (11)*]) at 24 through 36 weeks' gestation. The infant safety population included 3,568 and 3,558 infants born to individuals in the ABRYSV0 or placebo group, respectively. Among the infants born to individuals in the ABRYSV0 group and in the placebo group, 202 (5.7%) and 169 (4.7%), respectively, were born prematurely and

174 (4.9%) and 203 (5.7%), respectively, had reported congenital malformations or anomalies. There were 10 (0.3%) fetal deaths in the ABRYSV0 group and 8 (0.2%) in the placebo group.

Animal Data

A developmental toxicity study was performed in female New Zealand White rabbits. Rabbits were administered 4 doses by intramuscular injection: at 3 weeks and at 1 week prior to mating, and on gestation days 10 and 24. On each occasion, rabbits received 0.5 mL of a vaccine formulation containing twice the antigen content of F glycoproteins of RSV A and RSV B (120 mcg RSV preF A and 120 mcg RSV preF B), stabilized in prefusion conformation as contained in a single human dose of ABRYSV0 [see *Description (11)*]. No adverse effects on mating, female fertility, or on embryo/fetal or post-natal survival, growth, or development were observed. There were no vaccine-related fetal malformations or variations.

8.2 Lactation

Risk Summary

It is not known whether ABRYSV0 is excreted in human milk. Data are not available to assess the effects of ABRYSV0 on the breastfed infant or on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ABRYSV0 and any potential adverse effects on the breastfed child from ABRYSV0 or from the underlying maternal condition. For preventative vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine. ABRYSV0 is not approved for use in individuals younger than 60 years of age.

8.4 Pediatric Use

The safety and effectiveness of ABRYSV0 in individuals younger than 18 years of age have not been established.

8.5 Geriatric Use

ABRYSV0 is approved for use in individuals 60 years of age and older. In Study 1, of the 17,215 recipients who received ABRYSV0 62% (n=10,756) were aged 60-69 years of age, 32% (n=5,488) were 70-79 years of age and 6% (n=970) were ≥80 years of age [see *Adverse Reactions (6.1)* and *Clinical Studies (14.1)*].

11 DESCRIPTION

ABRYSV0 (Respiratory Syncytial Virus Vaccine) is a sterile solution for intramuscular injection. The vaccine is supplied as a vial of Lyophilized Antigen Component that is reconstituted at the time of use with a Sterile Water Diluent Component. The antigen component contains recombinant RSV preF A and RSV preF B.

The RSV preF A and RSV preF B recombinant proteins are expressed in genetically engineered Chinese Hamster Ovary cell lines grown in suspension culture using chemically-defined media, without antibiotics or animal-derived components. The recombinant proteins are purified through a series of column chromatography and filtration steps followed by formulation, filling into vials, and lyophilization.

After reconstitution, each dose of ABRYSV0 is approximately 0.5 mL. The vaccine is formulated to contain 120 mcg of RSV stabilized prefusion F proteins (60 mcg RSV preF A and 60 mcg RSV preF B) per 0.5 mL. ABRYSV0 also contains the following buffer ingredients: 0.11 mg tromethamine, 1.04 mg tromethamine hydrochloride, 11.3 mg sucrose, 22.5 mg mannitol, 0.08 mg polysorbate 80, and 1.1 mg sodium chloride per 0.5 mL. ABRYSV0 is a sterile, clear, and colorless solution.

ABRYSV0 contains no preservatives. Each dose may also contain residual amounts of host cell proteins ($\leq 0.1\%$ w/w) and DNA (< 0.4 ng/mg of total protein) from the manufacturing process.

The vial stopper and tip cap and rubber plunger of the prefilled syringe are not made with natural rubber latex.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

ABRYSV0 induces an immune response against RSV pre F that protects against lower respiratory tract disease caused by RSV.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

ABRYSV0 has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility. A developmental and reproductive toxicity study in female rabbits revealed no evidence of impaired female fertility [see *Use in Specific Populations* (8.1)].

14 CLINICAL STUDIES

14.1 Efficacy in Individuals 60 Years of Age and Older

Study 1 is an ongoing Phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of ABRYSV0 in the prevention of RSV-associated lower respiratory tract disease in individuals 60 years of age and older. Participants are planned to be followed for up to two RSV seasons, approximately 25 months.

Participants were randomized (1:1) to receive ABRYSV0 (n=17,197) or placebo (n=17,186). Randomization was stratified by age, 60-69 years (n=21,499, 63%), 70-79 years (n=10,948, 32%), and ≥ 80 years (n=1,934, 6%). Healthy adults and adults with stable chronic diseases were included. Among enrolled participants 15% had stable chronic cardiopulmonary conditions such as chronic obstructive pulmonary disease (COPD), asthma, or congestive heart failure (CHF).

Starting 14 days after study vaccination (study Day 15), all participants were actively monitored for onset of acute respiratory illness (ARI) symptoms: new or increased sore throat, nasal congestion, nasal discharge, cough, wheezing, sputum production, or

shortness of breath. If the participant experienced 1 or more ARI symptoms, a mid-turbinate nasal swab was collected within 7 days of onset of symptoms and tested by reverse transcriptase polymerase chain reaction (RT-PCR) for RSV.

RSV-associated lower respiratory tract disease (RSV-LRTD) was evaluated in Study 1. A case of RSV-LRTD was defined as an RT-PCR confirmed RSV illness with two or more, or three or more, of the following respiratory symptoms within 7 days of symptom onset and lasting more than 1 day during the same illness: new or increased cough, wheezing, sputum production, shortness of breath, or tachypnea (≥ 25 breaths/min or 15% increase from resting baseline). A case of RSV-associated severe lower respiratory tract disease was defined as a case meeting the RSV-LRTD criteria plus at least one of the following: hospitalization due to RSV-LRTD, new or increased oxygen supplementation, or mechanical ventilation including Continuous Positive Airway Pressure (CPAP).

Efficacy against Respiratory Syncytial Virus-associated Lower Respiratory Tract Disease

Vaccine efficacy (VE), against RSV-LRTD, defined as the relative risk reduction of first episode of RSV-LRTD in the ABRYSV0 group compared to the placebo group in the first RSV season, was assessed.

The study met the pre-specified success criteria for demonstration of efficacy of ABRYSV0 for the primary objectives of prevention of RSV-LRTD with ≥ 2 symptoms and prevention of RSV-LRTD with ≥ 3 symptoms. The median duration of follow-up for efficacy was 7 months.

Vaccine efficacy information is presented in Table 3.

Table 3 Vaccine Efficacy of ABRYSV0 Against RSV-LRTD - Individuals 60 years of Age and Older (Study 1)*

Efficacy Endpoint	ABRYSV0 N=16,306[†] n	Placebo N=16,308[†] n	VE (%) (96.66% CI)
First episode of RSV-associated lower respiratory tract disease with ≥ 2 symptoms	11	33	66.7 (28.8, 85.8)
First episode of RSV-associated lower respiratory tract disease with ≥ 3 symptoms	2	14	85.7 (32.0, 98.7)

CI - confidence interval; N - number of participants; n = number of cases; RSV - respiratory syncytial virus; VE - vaccine efficacy (VE based on case count ratio is calculated as $1-(P/[1-P])$, where P is the number of RSVpreF cases divided by the total number of cases)

* NCT05035212

† Evaluable efficacy population

There were 2 cases of RSV associated severe lower respiratory tract disease in the placebo group and no cases in the ABRYSV0 group.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

ABRYSVO is supplied in a kit that includes a vial of Lyophilized Antigen Component (NDC 0069-0207-01), a prefilled syringe containing Sterile Water Diluent Component (NDC 0069-0250-01) and a vial adapter. The Lyophilized Antigen Component is reconstituted with the Sterile Water Diluent Component to form a single dose of ABRYSVO.

ABRYSVO is supplied in cartons of 1, 5, and 10 kits.

Carton: 1 kit	NDC 0069-0344-01
Carton: 5 kits	NDC 0069-0344-05
Carton: 10 kits	NDC 0069-0344-10

The vial stopper and the tip cap and rubber plunger of the prefilled syringe are not made with natural rubber latex.

16.2 Storage and Handling

Storage Before Reconstitution

Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton. Do not freeze. Discard if the carton has been frozen.

Storage After Reconstitution

After reconstitution, administer ABRYSVO immediately or store at room temperature [15°C to 30°C (59°F to 86°F)] and use within 4 hours. Do not store reconstituted vaccine under refrigerated conditions [2°C to 8°C (36°F to 46°F)]. Do not freeze reconstituted vaccine.

17 PATIENT COUNSELING INFORMATION

Prior to administration of this vaccine:

- Inform vaccine recipient of the potential benefits and risks of vaccination with ABRYSVO.
- Advise vaccine recipient to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System at 1-800-822-7967 and www.vaers.hhs.gov.

This product's labeling may have been updated. For the most recent prescribing information, please visit www.pfizer.com.

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NY, NY 10001
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Pfizer Labs
Division of Pfizer Inc.
New York, NY 10001

LAB-1498-1.0

PRINCIPAL DISPLAY PANEL - 10 Vial/Syringe Kit Carton

NDC 0069-0344-10

Rx only

NOTICE: Lyophilized Antigen Component and Sterile
Water Diluent Component must be combined before use.

Respiratory Syncytial

Virus Vaccine

ABRYSVO™

For Intramuscular Use Only

Kit Contents (provides 10 doses of ABRYSVO™):

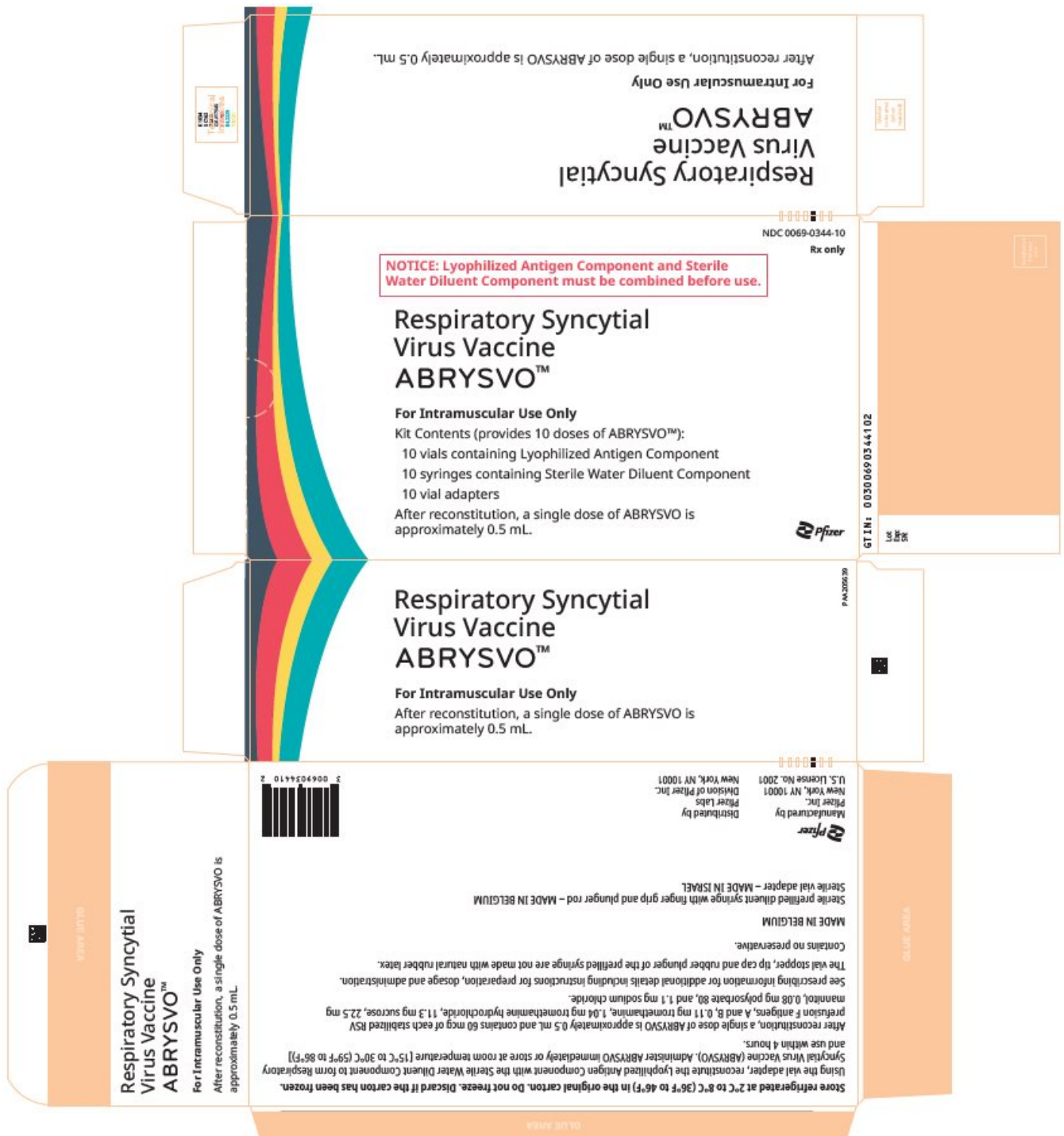
- 10 vials containing Lyophilized Antigen Component

- 10 syringes containing Sterile Water Diluent Component

- 10 vial adapters

After reconstitution, a single dose of ABRYSVO is
approximately 0.5 mL.

Pfizer



PRINCIPAL DISPLAY PANEL - 5 Vial/Syringe Kit Carton

NDC 0069-0344-05

Rx only

NOTICE: Lyophilized Antigen Component and Sterile Water Diluent Component must be combined before use.

Respiratory Syncytial
Virus Vaccine

For Intramuscular Use Only

5 vials containing Lyophilized Antigen Component

5 syringes containing Sterile Water Diluent Component

5 vial adapters

After reconstitution, a single dose of ABRYOVO is approximately 0.5 mL.

Pfizer



NDC 0069-0344-01

Rx only

NOTICE: Lyophilized Antigen Component and Sterile Water Diluent Component must be combined before use.

Respiratory Syncytial
Virus Vaccine
ABRYSVO™

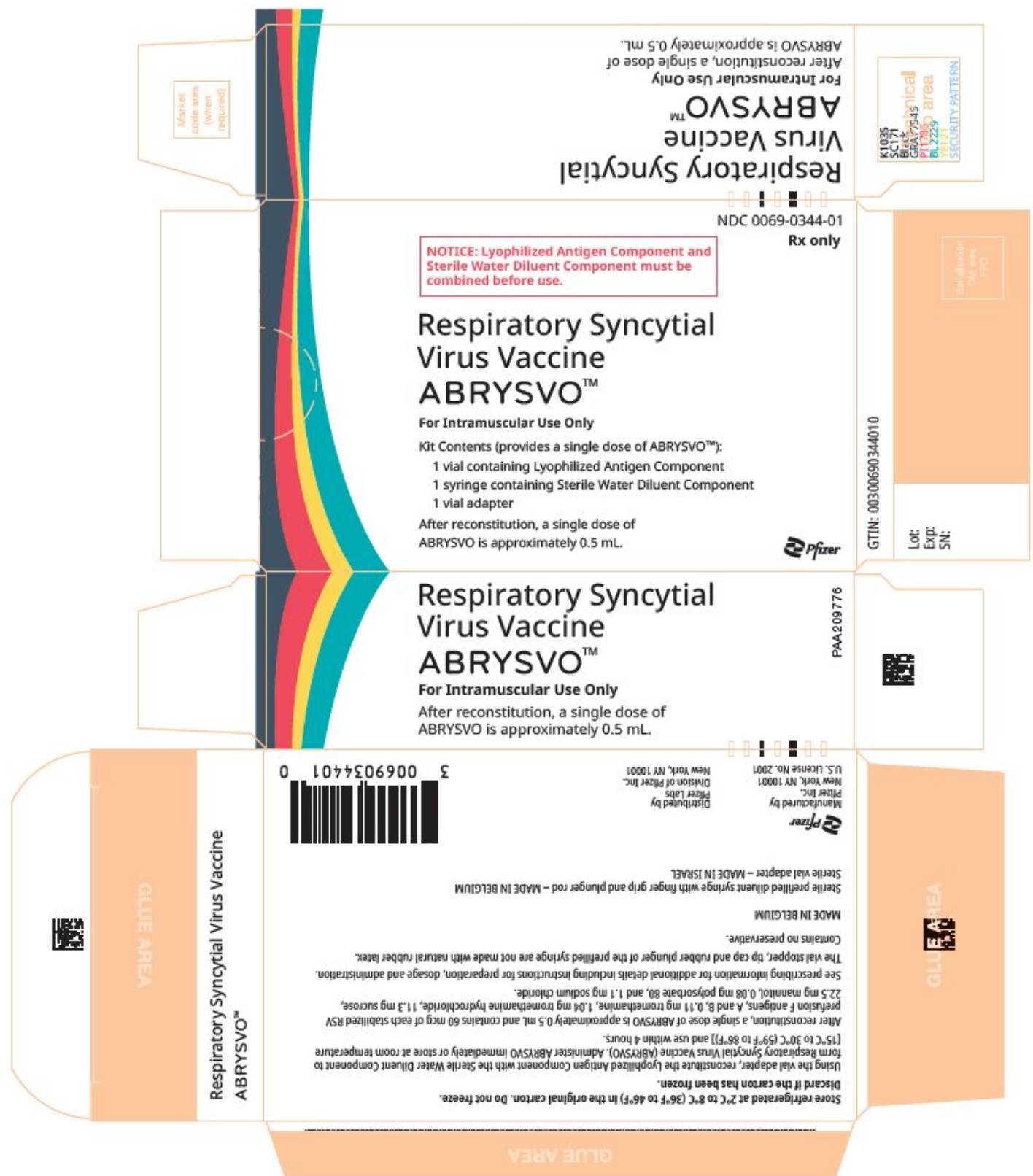
For Intramuscular Use Only

Kit Contents (provides a single dose of ABRYSVO™):

- 1 vial containing Lyophilized Antigen Component
- 1 syringe containing Sterile Water Diluent Component
- 1 vial adapter

After reconstitution, a single dose of
ABRYSVO is approximately 0.5 mL.

Pfizer



PRINCIPAL DISPLAY PANEL - 0.5 mL Vial Label

NDC 0069-0207-01

Rx only

Lyophilized Antigen Component

NOT TO BE USED ALONE

Reconstitute with Sterile Water Diluent

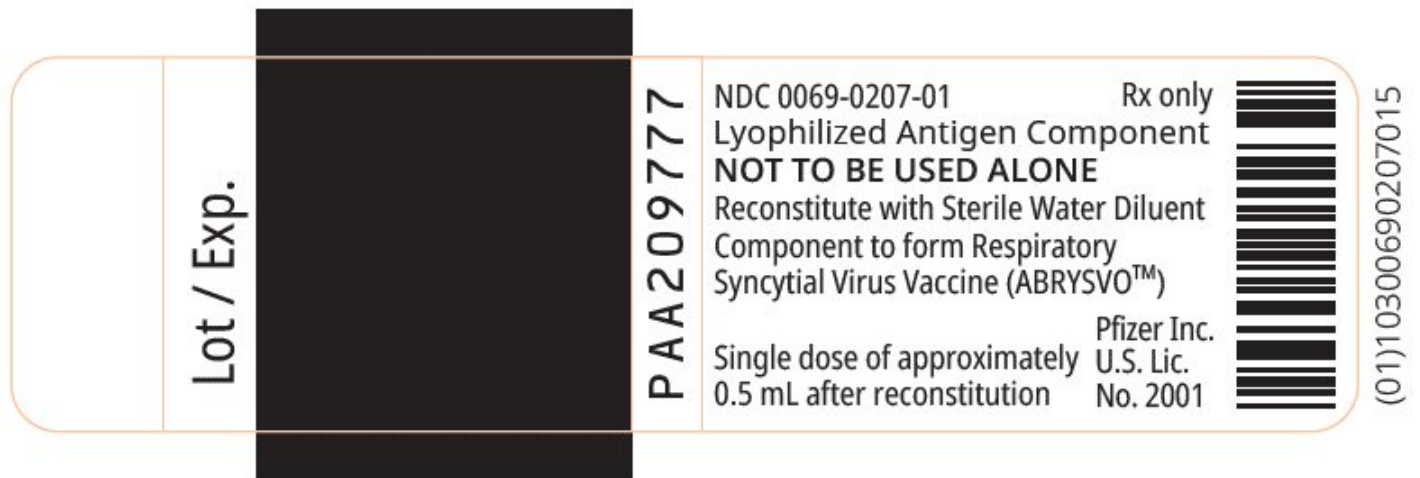
Component to form Respiratory
Syncytial Virus Vaccine (ABRYSVO™)

Pfizer Inc.

Single dose of approximately
0.5 mL after reconstitution

U.S. Lic.

No. 2001



PRINCIPAL DISPLAY PANEL - 1 Syringe Label

NDC 0069-0250-01

Sterile Water Diluent

Component

NOT TO BE USED ALONE

Add to 1 vial of Lyophilized
Antigen Component to
form Respiratory Syncytial
Virus Vaccine (ABRYSVO™)

U.S. Lic. No. 2001

Pfizer Inc.



Rx only

Lot:

Exp:

OVERPRINT

AREA

NDC 0069-0250-01	
Sterile Water Diluent Component	
NOT TO BE USED ALONE	
	Add to 1 vial of Lyophilized Antigen Component to form Respiratory Syncytial Virus Vaccine (ABRYSVO™)
	U.S. Lic. No. 2001
	Pfizer Inc.
	Rx only
PAA209778	
	
Lot: Exp:	OVERPRINT AREA

ABRYSVO

respiratory syncytial virus vaccine kit

Product Information

Product Type	VACCINE	Item Code (Source)	NDC:0069-0344
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0069-0344-01	1 in 1 CARTON		
1	NDC:0069-0344-21	1 in 1 TRAY; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
2	NDC:0069-0344-05	5 in 1 CARTON		
2	NDC:0069-0344-21	1 in 1 TRAY; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
3	NDC:0069-0344-10	10 in 1 CARTON		

3	NDC:0069-0344-21	1 in 1 TRAY; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
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Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL, GLASS	0.5 mL
Part 2	1 SYRINGE, GLASS	0.69 mL

Part 1 of 2

ABRYSVO

respiratory syncytial virus vaccine injection, powder, lyophilized, for solution

Product Information

Item Code (Source)	NDC:0069-0207
Route of Administration	INTRAMUSCULAR

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RECOMBINANT STABILIZED RSV A PREFUSION F ANTIGEN (UNII: 4PDL43Y9MR) (RECOMBINANT STABILIZED RSV A PREFUSION F ANTIGEN - UNII:4PDL43Y9MR)	RECOMBINANT STABILIZED RSV A PREFUSION F ANTIGEN	0.06 mg in 0.5 mL
RECOMBINANT STABILIZED RSV B PREFUSION F ANTIGEN (UNII: 34FS5XSD5Q) (RECOMBINANT STABILIZED RSV B PREFUSION F ANTIGEN - UNII:34FS5XSD5Q)	RECOMBINANT STABILIZED RSV B PREFUSION F ANTIGEN	0.06 mg in 0.5 mL

Inactive Ingredients

Ingredient Name	Strength
TROMETHAMINE (UNII: 023C2WHX2V)	0.11 mg in 0.5 mL
TROMETHAMINE HYDROCHLORIDE (UNII: 383V75M34E)	1.04 mg in 0.5 mL
SUCROSE (UNII: C151H8M554)	11.3 mg in 0.5 mL
MANNITOL (UNII: 3OWL53L36A)	22.5 mg in 0.5 mL
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.08 mg in 0.5 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	1.1 mg in 0.5 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0069-0207-01	0.5 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125769	07/12/2023	

Part 2 of 2

DILUENT SYRINGE FOR ABRYSSVO

sterile water diluent injection, solution

Product Information

Item Code (Source)	NDC:0069-0250
Route of Administration	INTRAMUSCULAR

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0069-0250-01	0.69 mL in 1 SYRINGE, GLASS; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125769	07/12/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125769	07/12/2023	

Labeler - Pfizer Laboratories Div Pfizer Inc (134489525)

Establishment

Name	Address	ID/FEI	Business Operations
Wyeth BioPharma Division of Wyeth		171250860	ANALYSIS(0069-0344) , API

Pharmaceuticals LLC		174550800	MANUFACTURE(0069-0344)
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Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Manufacturing Belgium NV		370156507	ANALYSIS(0069-0344) , MANUFACTURE(0069-0344) , PACK(0069-0344) , LABEL(0069-0344)

Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Ireland Pharmaceuticals		985586408	ANALYSIS(0069-0344)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		030606222	PACK(0069-0344) , LABEL(0069-0344)

Revised: 7/2023

Pfizer Laboratories Div Pfizer Inc